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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,733

08/09/2006

Toshiya Kai

NPR-190

3973

20374 7590 08/31/2010

KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/31/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,733	Applicant(s) KAI ET AL.	
	Examiner FRANK I. CHOI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kai et al. (US Pat. 6,464,977).

The claims are directed to a dry dialysate which contains sodium chloride, potassium chloride, calcium chloride, magnesium chloride and sodium acetate, where the sodium chloride can be coated with electrolytes not including calcium chloride or with electrolytes not including magnesium chloride.

Kai et al. disclose a dry dialysate containing a first composition containing sodium chloride coated with one or more of calcium chloride, magnesium chloride, potassium chloride and sodium acetate (Column 3, lines 25-30). A second composition is disclosed containing a sugar, such as glucose (Column 3, lines 33-35, Column 4, lines 14-16). It is disclosed that acetic acid can be added (Column 3, lines 20-29).

Kai et al. discloses a dry dialysate containing mixtures of coated sodium chloride electrolyte particles, glucose and acetic acid. The difference between Kai et al. and the claimed invention is that Kai et al. does not expressly disclose exclusion of calcium chloride in the first particle and magnesium chloride in the second particle. However, the prior art amply suggests the same as Kai et al. discloses that calcium chloride and magnesium chloride can be selected as

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coatings for the sodium chloride core. As such, one of ordinary skill in the art would have expected that sodium chloride particles which do not contain calcium chloride coating and sodium chloride particles which do not contain magnesium chloride coating would be suitable for use in the dry dialysate,

The Examiner has duly considered the Applicant's arguments but deem them unpersuasive.

As indicated above, the prior art suggests that the sodium chloride can be coated with electrolytes not including calcium chloride and electrolytes not including magnesium chloride. The Applicant argues that it is unexpected that sodium chloride coated with both is not equivalent to the separate coatings. However, the Applicant only presents a single comparative composition (the second comparative composition does not change the formulation of the coated sodium chloride) and two embodiments falling within the claimed invention. Further, the amounts of potassium chloride, calcium chloride, magnesium chloride and sodium acetate anhydride which form up the electrolyte coatings do not appear to be the same. As such, it cannot be concluded from the data that the separate coating of magnesium chloride and calcium chloride was the critical reason for the difference in dissolution and stability. Further, the claims do not indicate any specified amount of the components whereas the examples used specific amounts of the various components. As such, even if the data showed unexpected stability and dissolution characteristics, the data is not commensurate in scope with the claims.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the cited reference.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
August 30, 2010

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616